REMARKS

Claims 1-5, 7, 9-11 and 14-20 are currently pending. Claims 1-4, 7 and 9-19 are rejected and claims 5 and 20-23 are withdrawn from consideration.

No new matter has been added by way of the present submission. For instance, claims 12 and 13 have been cancelled and claim 1 has been amended. Support for the amendment to claim 1 may be found in claim 12 and 13 as filed as well as the present specification at page 13, lines 1-15 and 17-21. Thus, no new matter has been added.

Further, no new issues have been raised. In particular, Applicants have included the textual subject matter of claims 12 and 13 into claim 1. Since these claims are already searched and considered, the Examiner is not now presented with any additional burden of search and/or consideration.

In the event that the present submission does not place the application into condition for allowance, entry thereof is respectfully requested as placing the application into better form for appeal.

In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

Issues under 35 U.S.C. § 112, first paragraph

The Examiner has rejected claims 1-3, 9-11, 15 and 17 under 35 U.S.C. § 112, first paragraph for the reasons cited at pages 3-5 of the outstanding Office Action. Applicants respectfully traverse.

(i) As to the rejections concerning the lipid and polymer, Applicants submit that these rejections have been rendered moot by way of the above amendment. Reconsideration and withdrawal thereof are thus requested.

(ii) As to the rejections concerning the emulsifier and water soluble drug, Applicants submit that the Examiner's rejections are improper.

The technical feature of the present invention does not rest on the specific kinds of emulsifier and water soluble drug. Indeed, the present specification describes diverse examples of emulsifier (see page 14, lines 8-19 of the present specification), and their use for

stabilizing the dispersion (see page 14, 17-19), and the water soluble drug (particularly, see page 11, lines 19 to 21).

Thus, a skilled artisan can easily understand that the nanoparticle composition can he prepared by using those described in the present specification or equivalents thereof, and can select any emulsifier which can stabilize the particle so that they do not cluster with each other.

Also, any drug which is water soluble and ionic in water can be applied to prepare the present composition by using the specific kinds of counter-ion, lipid and polymer described in claim 1 as amended, and then can enjoy the advantageous effects of the present invention.

As such, Applicants submit that claim 1 as amended is fully enabled since those of ordinary skill in the art are able to make and use this invention without undue experimentation. The Examiner is thus requested to withdraw this rejection.

Issues under 35 U.S.C. § 102

The Examiner has rejected claims 1, 2, 7, 11-15 and 17-19 under 35 U.S.C. § 102 as being anticipated by EP0771566 (hereinafter referred to as EP '566). Applicants respectfully traverse this rejection.

The present invention becomes more distinguishable from EP '566 by the above amendment to claim 1, and EP '566 fails to suggest or disclose the presently claimed invention as explained in detail below:

EP '566 uses an "oil in water emulsion" system to prepare the composition. In EP '566, the ionic complex forms a film at the interface of a colloidal system, and the drug is incorporated into the oil core. That is, EP '566 relates to a colloidal system including the incorporation of water soluble positively charged amino polysaccharides and negatively charged phospholipids (see abstract).

In contrast, in the present invention, the drug reacts with the counter-ion substance to form a complex, and then the neutralized complex is entrapped by hydrophobic bonding between the lipid and polymer. There is no ionic complex formation between the lipid and polymer. The neutralized complex of the drug and the counter-ion is surrounded by the lipid, i.e., the present system is NOT an emulsion. In the present system, the drugs are entrapped with lipids or

polymers and thus not exposed to external chemical environment, e.g. pH or digestive enzymes. In this regard, the present specification describes that "[0004] *For example, orally administrable formulations for water-soluble drugs using w/o or w/o/w emulsion, or liposome are known in the art. However they have drawbacks of having insufficient drug entrapping rate and low stability.*"

In summary, EP '566 fails to suggest or disclose the presently claimed subject matter. Indeed, EP '566 is simply one of the prior arts having problems to be solved by the present invention. Thus, the presently claimed composition is not anticipated by the EP '566 colloidal system (emulsion). The Examiner is thus requested to withdraw this rejection.

Issues under 35 U.S.C. § 103(a)

The Examiner has rejected claims 1-4, 7 and 9-19 under 35 U.S.C. § 103(a) as being obvious over WO2004/043513 (hereinafter referred to as WO '513). Applicants respectfully traverse this rejection.

WO '513 fails to suggest or disclose the present ionic complex of drug and counter-ion and the present lipid/polymer system surrounding ionic complex. Thus, specific limitations of the claims are completely absent from WO '513. Thus, there can be no obviousness. The Examiner is thus requested to withdraw this rejection.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Craig A. McRobbie, Reg. No. 42,874 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

By _____

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